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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/307,195	05/07/1999	WILLIAM COHN	BIH97-04A2	4520

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EXAMINER

SMITH, JEFFREY A

ART UNIT PAPER NUMBER

3625

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/307,195

Applicant(s)

COHN, WILLIAM

Examiner

Jeffrey A. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-24 and 37-40 is/are allowed.
- 6) ☒ Claim(s) 1-14, 16, 17, 25-36 and 41-50 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 May 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Response to Amendment

The response deposited 15 January 2003 to the Office Action mailed 15 July 2002 has been entered.

Claims 1 and 25 have been amended by such response. Claims 1-50 remain pending and an action on the merits of such claims follows.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-10, 12-14, 16, 25-27, 29-34, 36, 41, 42, and 44-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Benetti et al. (U.S. Patent No. 5,894,843).

Benetti et al. discloses (Fig. 7) a surgical device (60) comprising a retaining element (62) having an aperture (61); a

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connector ("suture line": col. 12, line 27); a plurality of suture holders (70); a handle (69); and a tab (63).

A method including the steps of positioning, occluding, and connecting are disclosed (col. 12, lines 5-27).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 11, 17, 28, 35, 43, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benetti et al. (U.S. Patent No. 5,894,843).

Although Benetti et al. does not disclose irrigation or suction, it would have been obvious to one of ordinary skill in the art to have provided the device reported above to have included such structure because the use of irrigation and suction are well-known for use during surgeries of the type disclosed by Benetti et al.

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Allowable Subject Matter

Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 18-24, and 37-40 are allowed.

Response to Arguments

Applicant's arguments deposited 15 January 2003 have been fully considered but they are not persuasive.

Applicant remarks at page 3 of the response deposited 15 January 2003:

"The only method for artery compression that is described in Benetti involves the downward force exerted by the occluder 63 in the aperture 61. This structure is not identical nor does it have 'similar utility'."

The Examiner does not find such remarks to be persuasive as they apply to "apparatus" claims defined by independent claims 1, 25, and 41.

The Examiner first notes that that the functional language recited does not invoke 35 USC 112, 6th paragraph.

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The Examiner agrees that Benetti et al. '843 does not disclose the method step of compressing the artery between the connector and the retaining element (such as recited in claim 18). However, actual disclosure of such step is not required in anticipation of claims drawn to the "apparatus". What is required is that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, claims 1, 25, and 41 merely functionally set forth the features being argued.

For example:

claim 1 recites:

"the connector compresses and occludes the artery against a surface on the retaining element that is positioned on a second side of the artery at a first arterial position on a first side of the operative site and at a second arterial position on a second side of the operative site" (emphasis added);

claim 25 recites:

"artery tissue can be compressed and occluded between the cord that extends on a first side of the artery and the retaining base that is positioned on a second side of the

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artery and held stationary relative to the retaining base with the cord and the cord retainer"(emphasis added); and

claim 41 recites:

"the cord compresses and occludes a coronary artery positioned between the cord and a portion of the retaining base"(emphasis added).

The Examiner notes that the amendments to claims 1 and 25 to place certain structure relative to the human anatomy do not move to further define the structure of the apparatus. This is because the anatomy itself is not and cannot be claimed as part of the "apparatus". The anatomy serves only as a landmark to assist in establishing where the recited structural elements are to be placed.

In weighing the language of the apparatus claims the Examiner has adhered to the guidance provided by the Courts in *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963) and maintains that the device (or retractor) disclosed by Benetti is reasonably capable of performing the recited functions.

Benetti et al. '843 is replete with reference to devices (or retractors) comprising a holder on a retaining element (or base) that holds a connector (i.e. a suture line) that positions the connector to compress the cardiac tissue of the operative

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site against a retaining element surface. Although Benetti et al. does not expound upon port 70 in their description of the embodiment of Fig. 7, they do refer to such port's utility (i.e. "for receiving a suture line" (col. 12, lines 26-27)). Benetti et al. details the full utility of such suture line receiving port in reference to previous embodiments (see col. 10, lines 57-62; col. 11, lines 19-30; col. 11, line 60-col. 12, line 4). Benetti et al. further teaches that "[i]n some embodiments, as described herein, the contact members 1 may have apertures, openings or attachments to facilitate connection with sutures or other devices to achieve the requisite stabilization" (col. 7, lines 20-24).

The Examiner believes that the entirety of the single Benetti et al. disclosure anticipates Applicant's claims because the disclosure reasonably teaches the full capability of the ports 70 as for receiving a suture line for administering the requisite stabilization of the operative site (e.g. cardiac tissue (col. 11, line 67-col. 12, line 4)) and for depressing the tissue adjacent the target artery (col. 11, lines 27-30).

Applicant's remarks that "it is not possible to use a suture line with the ports 70 to compress the artery exposed in aperture 61 (Benetti, Fig. 7) against element 62 or occluders 63

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without damaging the artery". Applicant further remarks that "[i]f a suture line were used as suggested in the Office Action in the device of Fig. 7 in Benetti, this would likely cause the artery to snake around the occluder 63 and the suture line, thereby increasing the risk of injury".

The Examiner believes that both hypothetical scenarios leave standing the interpretation that Benetti is reasonably capable of performing the recited functions. The interpretation of Benetti is unaffected by the actual desire of the skilled artisan to perform the recited functions or by the probabilities of success using the recited functions.

Notwithstanding this, however, Benetti fully appreciates the need to engage the artery without damaging the tissue (col. 12, lines 11-14). It is not reasonable to believe, in light of this teaching, that any of Benetti's techniques employing suture lines to stabilize the artery (as per col. 11, line 67-col. 12, line 4, for example) are performed without recognition that the artery should be engaged without damaging the artery. And, it is not reasonable to believe that Applicant's scenarios in an attempt to perform the functions of the recited claims would necessarily result in damage to the artery. The same caution taught by Benetti to avoid damaging the artery would have


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applied--even to the hypothetical scenarios advanced by Applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey A. Smith whose telephone number is 703-308-3588. The examiner can normally be reached on M-F 6:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wynn Coggins can be reached on 703-308-1344. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7687 for regular communications and 703-308-3691 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.


Jeffrey A. Smith
Primary Examiner
Art Unit 3625

jas
April 6, 2003